

**REPLY UNDER 37 C.F.R. §1.116**  
**EXPEDITED PROCEDURE**  
**GROUP ART UNIT 1646**



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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Patent Application of

Fabrizio SAMARITANI et al.

Date: September 7, 2000

Serial No.: 08/737,633

Group Art Unit: 1646

Filed: November 15, 1996

Examiner: D. Fitzgerald

For: IFN-BETA LIQUID FORMULATIONS

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Assistant Commissioner for Patents  
BOX AF  
Washington, D.C. 20231

**REPLY UNDER 37 C.F.R. §1.116 TO MARCH 7, 2000 FINAL OFFICE ACTION**

Sir:

In reply to the final Office Action dated March 7, 2000, please reconsider the above-identified application in view of the following remarks.

**REMARKS**

Claims 1 and 3-10 were pending in this application. According to the March 7, 2000 Office Action, claims 1 and 3-10 were finally rejected.

**Rejection under 35 U.S.C. §103(a)**

The Examiner maintained his rejection of claims 1, 3, 7, 9 and 10 under 35 U.S.C. §103(a) as allegedly unpatentable over U.S. Patent No. 5,643,566 (Hanisch). The Examiner also maintained his rejection of claim 5 under 35 U.S.C. §103(a) as allegedly unpatentable over Hanisch in view of U.S. Patent No. 4,647,454 (Cymbalista). The Examiner further maintained his rejection of claim 6 under 35 U.S.C. §103(a) as allegedly unpatentable over Hanisch in view of U.S. Patent No. 5,004,605 (Hershenson).

In response, Applicants respectfully traverse the Examiner's rejection. The present invention relates to a **liquid** pharmaceutical formulation consisting of from 0.6 to 24 MIU/ml of interferon-beta, **mannitol**, a buffer at a **pH between 3.0 and 4.0** and, optionally, albumin. In

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